

Analysis of Breastlight Findings in Patients with Biopsies

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Breastlight is a new product which is designed to be used as an aid to breast awareness by women at home. Breastlight is a handheld device that transilluminates the breast with a red light (617nm) that is absorbed by haemoglobin so that areas of high vascularity (such as malignant tumours) should appear black. Clinical trials with its prototype in Edinburgh and Aberdeen had a sensitivity of 70-90%.

The current version of Breastlight was evaluated on 300 subjects who were referred to the breast clinic in Sunderland for a variety of reasons. All subjects had both breasts examined using Breastlight. The researchers retrospectively identified the index breast for which women had been referred by her GP.

In the 300 patients recruited to complete the study, 58 biopsies were performed (two women had both breasts biopsied). A diagnosis of cancer was made in 18 women and a variety of benign diagnoses was made in 40 biopsies.

Cancer present on biopsy:

Breastlight showed a shadow on direct imaging in 12/18 breasts giving a sensitivity of 67%. These tumours varied in size from 0.7 – 3.8 cm. Breastlight was negative in 6/18 breasts with a malignant tumour. These tumours varied in size from 1.6 – 3.6 cm.

The type of cancer appeared not to be a factor. 7/11 ductal cancers were positive. 3/4 lobular cancers were positive. One Non Hodgkins Lymphoma and one papillary carcinoma were positive. One mixed cancer was negative.

Cancer absent on biopsy:

Seven of 40 benign breast biopsies were positive on Breastlight. There are a wide variety of diagnoses so any relationship is unlikely to be demonstrable. Some benign conditions might be expected to have been positive on Breastlight because of the presence of residues of bleeding e.g. haematoma following trauma.

In the non index breasts there were seven positive Breastlight results (assumed false positive) out of 220 screened – a figure of 3.2%.

We are encouraged by the results of this trial. It appears that Breastlight is effective in the detection of malignant tumours and in some cases can differentiate between malignant and benign disease. This device will prove to be of particular value to women who difficulty in self examination – for example those with a history of recurrent cysts.

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